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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,553	09/27/2001	David A. Wright	900.175US2	5748

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EXAMINER	
MEHTA, ASHWIN D	

ART UNIT	PAPER NUMBER
1638	12

DATE MAILED: 08/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/965,553	WRIGHT ET AL.	
	Examin r	Art Unit	
	Ashwin Mehta	1638	

-- The MAILING DATE of this communication appears n the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49-108* is/are pending in the application.

4a) Of the above claim(s) *57-59,61-68,73-76 and 79-107* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49-56,60,69-72,77,78 and 108* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group IV, claims 49-56, 60, 69-72, 77, 78, and 108 in Paper No. 10, submitted 27 May 2003, is acknowledged. The traversal is on the ground(s) that: Applicants submit that the claims are directed towards the nucleic acids encoding the components of a retroelement, and that a search of one of the nucleic acids would result in a search of one or more of the other claimed nucleic acids, and that it would not be an undue burden on the Examiner to search the claimed nucleic acids. This is not found persuasive because the claims do not place any limitations on the nucleic acids that can comprise sequences set forth in the indicated sequence identifiers. A search of one sequence would not necessarily result in a search of any other sequence.

The requirement is still deemed proper and is therefore made FINAL. Claims 57-59, 61-68, 73-76, 79-107 have been withdrawn as being drawn to non-elected inventions.

Specification

2. The specification fails to comply with the sequence rules of 37 CFR 1.821-1.825. Numerous sequences appear on pages 43, 45, and 53-56 that must be referred to by their sequence identifiers.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 49, 50, 52-56, and 69-71 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,331,662 ('662). Although the conflicting claims are not identical, they are not patentably distinct from each other because isolated nucleic acids of the patented and instant claims comprise the nucleotide sequences set forth in SEQ ID NO: 2 and SEQ ID NO: 11. The instant claims encompass any isolated nucleic acids that comprise SEQ ID NO: 2, or those that comprise SEQ ID NO: 2 and SEQ ID NO: 11, and seeds and plants that comprise the nucleic acids. Claims 1-3 of '662 encompass isolated nucleic acid molecules that comprise the nucleotide sequence of SEQ ID NO: 17, and seeds and plants that comprise said isolated nucleic acid. SEQ ID NO: 17 of '662 comprises instant SEQ ID NO: 2 and SEQ ID NO 11.

4. Claims 49 and 56 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/315,515 ('515). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of both applications encompass the same subject

matter. Instant claim 49 encompasses any isolated nucleic acid comprising the nucleotide sequence set forth in SEQ ID NO: 1 or SEQ ID NO: 2. Claim 1 of '515 encompasses any isolated retroelement comprising any sequence that is at least 90% identical to SEQ ID NO: 122. The sequence of SEQ ID NO: 122 of '515 comprises instant SEQ ID NO: 1. The isolated retroelement of claim 1 of '515 then can be considered to be a nucleic acid that comprises instant SEQ ID NO: 1. SEQ ID NO: 122 of '515 comprises gag, pol, and env genes, wherein the gag gene has an ATG start codon.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 77 and 78 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 77: the recitation, "encodes at least one agronomically-significant characteristic" renders the claim indefinite. A nucleic acid does not encode characteristics.

Further in claim 77: it is not clear what agronomic trait is referred to by the recitation, "self-incompatibility." It is also not clear what is meant by the agronomically-significant characteristics of "a photosynthetic pathway, fruit ripening, oil biosynthesis, pigment

biosynthesis, seed formation, starch metabolism." Is the isolated nucleic acid to encode all of the genes involved at least one of these processes? The metes and bounds of the claim are not clear.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 49-56, 60, 69-72, 77, 8, and 108 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn towards any isolated nucleic acid comprising SEQ ID NO: 1 or 2; or an isolated nucleic acid selected from the group consisting of: (a) any nucleic acid having at least 95% identity to SEQ ID NO: 2; (b) any nucleic acid having SEQ ID NO: 2; and (c) any nucleic acid complementary to SEQ ID NO: 2; or a vector that can transfer said nucleic acid to any plant cell; any seed or plant comprising said nucleic acid; or wherein said nucleic acid further comprises gag, pol, and env genes, wherein the gag gene comprises an ATG start codon; or wherein the nucleic acid further comprises a nucleic acid selected from the group consisting of: (a) any nucleic acid having at least 70% identity to SEQ ID NO: 11 and encoding a reverse transcriptase; (b) any nucleic acid having SEQ ID NO: 11; (c) any nucleic acid encoding any amino acid sequence having at least 79% identity to SEQ ID NO: 12 and encoding a reverse

transcriptase; (d) any nucleic acid encoding SEQ ID NO: 12; and (e) any nucleic acid having a sequence fully complementary to (a), (b), (c), or (d); or wherein said nucleic acid further encodes at least one agronomically-significant characteristic; or a method to transfer said nucleic acid into any plant cell.

The specification indicates that the Calypso-1, -2, and -3 retrovirus-like elements were aligned using the ClustalX v1.63b program to generate a consensus sequence. The amino acid sequence encoded by the consensus sequence was determined and compared to amino acid sequences of retrovirus-like elements from soybean, pea (Cyclops2), and *Athila*-like elements of Arabidopsis. A new consensus sequence was determined for the coding regions of the protease, reverse transcriptase, and integrase (pages 56-57, Example 4). A summary of the sequence listing on pages 19-20 indicates that SEQ ID NOs: 1 and 2 are specialized primer binding site versions 1 and 2, respectively, and that SEQ ID NO: 11 is the nucleic acid of a generic reverse transcriptase, the amino acid sequence of which is set forth in SEQ ID NO: 12.

However, the specification does not describe all isolated nucleic acids that comprise SEQ ID NO: 1 or 2. As broadly interpreted, the claim encompasses any isolated nucleic acid, encoding any product and having any function, as long as it comprises SEQ ID NO: 1 or SEQ ID NO: 2. The specification does not describe the structures or functions of all isolated nucleic acids that comprise SEQ ID NOs: 1 or 2. SEQ ID NOs: 1 and 2 are described simply as sites to which primers may bind, and provide no information at all about the structures and functions of other sequences that comprise them. The claims also do not describe any nucleic acid sequences that have at least 70% identity with SEQ ID NO: 11, or which encode amino acid sequences having at least 79% identity with SEQ ID NO: 12, and which encode reverse transcriptases. The

specification does not describe the changes that can be made to SEQ ID NOs: 11 or 12, such that nucleotide sequences that differ from SEQ ID NO: 11 by as much as 30% and amino acid sequences that differ from SEQ ID NO: 12 by as much as 21%, still retain their functional properties. See Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene is not obtained until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence). Also see *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997), where it states: "The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA... Accordingly, the specification does not provide a written description of the invention..." Also see Fiers v. Revel 25 USPQ 2d (CAFC 1993) at 1606, which states that "[a]n adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself".

Further, claim 56 limits the isolated nucleic acid of claims 49 or 50 to further comprise gag, pol, and env genes. However, all env genes are not described, and the function of env genes of plant LTR retroelements is not known. Peterson-Burch et al. (TIG, 2000, Vol. 16, pages 151-152), referring to possible env-like genes of a few plant retroelements, state "Defining the function of the env-like ORFs is the next task at hand" (page 152). This indicates that the function of the putative env genes was not known at the time instant invention was filed, and the

instant specification does not describe all env genes. Furthermore, the specification does not describe any isolated nucleic acids that encode "self-incompatibility" in plants, or all of the genes that are involved in the traits listed in claim 77. The claim encompasses genes that have yet to be isolated, which therefore cannot be described. Given the breadth of the claims encompassing all isolated nucleic acids encompassing SEQ ID NO: 1 or 2, all nucleic acids having at least 70% identity to SEQ ID NO: 11 or encoding amino acid sequences having at least 79% identity to SEQ ID NO: 12, and all genes involved in all of the traits listed in claim 77, and the lack of written description as discussed above, the specification fails to provide an adequate written description of the multitude of isolated nucleic acids encompassed by the claims.

7. Claims 49-56, 60, 69-72, 77, 78, and 108 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO: 1, SEQ ID NO: 2, and nucleotide sequences encoding SEQ ID NO: 12, does not reasonably provide enablement for all isolated nucleic acids comprising SEQ ID NO: 1 or SEQ ID NO: 2, nucleic acid sequences that have at least 70% identity with SEQ ID NO: 11 or which encode amino acid sequences having at least 79% identity with SEQ ID NO: 12, vectors that can transfer nucleic acids to plant cells comprising the claimed isolated nucleic acids, isolated nucleic acids involved in all of the characteristics listed in claim 77, and a method to transfer nucleic acid into a plant cell, comprising contacting the claimed nucleic acids with at least one plant cell. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn towards any isolated nucleic acid comprising SEQ ID NO: 1 or 2; or an isolated nucleic acid selected from the group consisting of: (a) any nucleic acid having at least 95% identity to SEQ ID NO: 2; (b) any nucleic acid having SEQ ID NO: 2; and (c) any nucleic acid complementary to SEQ ID NO: 2; or a vector that can transfer said nucleic acid to any plant cell; any seed or plant comprising said nucleic acid; or wherein said nucleic acid further comprises gag, pol, and env genes, wherein the gag gene comprises an ATG start codon; or wherein the nucleic acid further comprises a nucleic acid selected from the group consisting of: (a) any nucleic acid having at least 70% identity to SEQ ID NO: 11 and encoding a reverse transcriptase; (b) any nucleic acid having SEQ ID NO: 11; (c) any nucleic acid encoding any amino acid sequence having at least 79% identity to SEQ ID NO: 12 and encoding a reverse transcriptase; (d) any nucleic acid encoding SEQ ID NO: 12; and (e) any nucleic acid having a sequence fully complementary to (a), (b), (c), or (d); or wherein said nucleic acid further encodes at least one agronomically-significant characteristic; or a method to transfer said nucleic acid into any plant cell.

As discussed above, the specification indicates that the Calypso-1, -2, and -3 retroelements were aligned using the ClustalX v1.63b program to generate a consensus sequence. The amino acid sequence encoded by the consensus sequence was determined and compared to amino acid sequences of retrovirus-like elements from soybean, pea (Cyclops2), and *Athila*-like elements of Arabidopsis. A new consensus sequence was determined for the coding regions of the protease, reverse transcriptase, and integrase (pages 56-57, Example 4). A summary of the sequence listing on pages 19-20 indicates that SEQ ID NOs: 1 and 2 are specialized primer

binding site versions 1 and 2, respectively, and that SEQ ID NO: 11 is the nucleic acid of a generic reverse transcriptase, the amino acid sequence of which is set forth in SEQ ID NO: 12.

However, the specification does not teach all isolated nucleic acids that comprise SEQ ID NO: 1 or 2. As discussed above, the claims broadly encompass any and all nucleic acids having any function, as long as they comprise SEQ ID NO: 1 or 2. However, the specification does not teach all such isolated nucleic acids. See Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1027, where it is taught that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof. Also see In re Bell, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and In re Deuel, 34 UPSQ2d, 1210 (Fed. Cir. 1995), which teach that the mere existence of a protein does not enable claims drawn to a nucleic acid encoding that protein. Further, SEQ ID NOs: 1 and 2 are primer binding sites. No other function for these sequences is taught. How one is to use all isolated nucleic acids that comprise these sites is not clear. See also Genentech, Inc. V. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention. The specification also does not teach nucleic acid sequences that have at least 70% identity with SEQ ID NO: 11 or which encode amino acid sequences having at least 79% identity with SEQ ID NO: 12. The specification does not teach what amino acid sequences of SEQ ID NO: 12 may be changed without affecting its reverse transcriptase activity. Further, the specification does not teach how one would use an isolated nucleic acid comprising SEQ ID NO: 1 or 2, or the complement of SEQ ID NO: 2, and the complement of (a)-(d) of claim 69. The use of such a nucleic acid is not obvious, nor taught in the specification. See Genentech, Inc. V. Novo Nordisk, A/S, *supra*.

Further, the specification does not enable the claimed vectors, or claimed method. First, the claims broadly encompass introducing isolated nucleic acid sequences consisting of only SEQ ID NO: 1, or SEQ ID NO: 2, the complement of SEQ ID NO: 2, or further comprising the nucleic acids of parts (a)-(e) of claim 69, into plant cells. Again, as SEQ ID NOs: 1 and 2 are primer binding sites, and SEQ ID NO: 12 is a reverse transcriptase, it is not clear how one would use plant cells that were transformed only with these sequences or their complements, nor is this explained in the specification. The specification also prophetically indicates that methods are provided to transfer nucleic acids into plant cells, comprising contacting a plant retroelement with a plant cell (page 14). The specification prophetically indicates that a generic retroelement will be modified so that it will express at high levels in plant cells, and because the modified generic element will be expressed at high levels, retroviral particles will be produced by the host plant cell, which will be incubated in the presence of non-transformed plant cells, and that the virus will associate with the plant cell and fuse with the cell membrane (page 57). However, the specification does not teach that any retroelement was successfully used to transfer nucleic acids of interest into plant cells. Peterson-Burch et al. teach that the role of env-like open reading frames of plant retroviruses can *now* be tested (page 152, emphasis added). Vicient et al. (Genome Research, 2001, Vol. 11, pages 2041-2049) assert that, while ENV of Bagy-2 and other retrotransposons are active, that the question of function remains uncertain, and that a replication or infection-competent plant errantivirus must be identified and its life cycle characterized in order to resolve the question of ENV function in plants (page 2046). These teachings indicate that further basic research is required before one skilled in the art can use the claimed nucleic acids with the claimed vectors and with the claimed method. Wright et al. (Genome Research,

2001, Vol. 12, pages 122-131) also stress that "The identification of a replication-competent *Athila* group element will be necessary to test the hypothesis that these elements are infectious plant retroviruses. If this proves to be the case, the *Athila* group elements may be useful as vectors for gene transfer and the genetic modification of plants" (page 130). This also indicates that further research is required to enable the claimed invention. In the absence of further guidance, undue experimentation would be required to use the claimed vectors or practice the claimed method.

Further, the specification does not teach isolated nucleic acids that confer all of the traits listed in claim 77 when expressed in a genetically-engineered plant. The specification does not teach genes involved in self-incompatibility, all genes involved in improving all biosynthetic pathways in all plants, nor how to improve photosynthetic pathways, seed formation, or improve tolerance to anaerobic conditions. See In re Bell, In re Deuel, and Genentech, Inc. V. Novo Nordisk, A/S, *supra*. Given the breadth of the claims, unpredictability of the art, and lack of guidance of the specification, as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Rounsley et al. (EST or GenBank Database Accession No. B62585, Nov. 1997).

The claim is broadly drawn towards any isolated nucleic acid comprising SEQ ID NO: 1 or SEQ ID NO: 2.

Rounsley et al. teach a nucleotide sequence that comprises the complement of SEQ ID NO: 1. The reference inherently teaches the complement of this sequence, which comprises SEQ ID NO: 1.

9. No claim is allowed.

Contact Information

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

August 21, 2003

Ashwin D. Mehta, Ph.D.
Primary Examiner
Art Unit 1638